



Food and Drug Administration Rockville MD 20857

Re: Vimpat

Docket Nos. FDA-2009-E-0172

FDA-2009-E-0173 FDA-2009-E-0174

FDA-2009-E-0175

The Honorable David J. Kappos Under Secretary of Commerce for Intellectual Property Director of the United States Patent and Trademark Office Mail Stop Hatch-Waxman PTE P.O. Box 1450 Alexandria, VA 22313-1450

Dear Director Kappos:

SEP 2 9 2009

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,654,301 and RE38,551 filed by Research Corporation Technologies, Inc., under 35 U.S.C. § 156. The human drug product claimed by the patents is Vimpat (lacosamide), which was assigned new drug application (NDA) Nos. 22-253 and 22-254.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The NDAs were approved on October 28, 2008, which makes the submission of the patent term extension applications on December 23, 2008, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review periods, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Associate Director for Policy

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Center for Drug Evaluation and Research

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cc: Kevin G. Shaw
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004